

REMARKS

Copies of the Formal figures 1 and 2 are supplied herewith addressing the Draftperson's objections of October 10, 2002. Originals are concurrently being mailed to Commissioner for Patents, United States Patent Office Alexandria, VA 22313-1450.

Claims 6, 10-12, and 15-22 were pending. Claim 21 was allowed. Applicants have hereby canceled all pending claims without prejudice to further prosecution in a continuing application and have added new claims 23-36 in order to expedite an early issuance of additional claims from this application. The subject matter of new claim 30 corresponds to that of allowed claim 21.

New claims 23-27 recite synthetic immunogens comprising one the fully described and exemplified GnRH peptide sequences (amino acids 1-10 or 2-10 of SEQ ID NO: 1) linked through one of the fully described and enabled spacer peptide sequences (SEQ ID NO: 5, SEQ ID NO: 6 or SEQ ID NO: 7) to one of the described and enabled T-lymphocyte helper epitopes (SEQ ID NO: 8 of measles virus protein F (MVP-F), or SEQ ID NO: 2 or SEQ ID NO: 4 of tetanus toxoid (TT), and SEQ ID NO: 3 of malaria circumsporozoite protein (M-CSP).

New claims 28 and 29 recite a synthetic immunogen having the described and enabled amino acid sequences of any of SEQ ID NOS:9-20.

New claim 30 recites a mixture of synthetic immunogens having the amino acid sequences of SEQ ID NOS:10 and 11. New claim 31 recites a mixture of synthetic immunogens having the amino acid sequences of any two of SEQ ID NOS:9-20.

New claims 32-36 recite injectable pharmaceutical compositions of the above-identified synthetic immunogens and mixtures of synthetic immunogens.

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In the office action of October 6, 2003 the examiner rejected claims 6, 10, 15 and 17-20 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. Claims 6, 10, 15 and 17-20 have been cancelled and therefore this rejection is moot.

However, in the office action the examiner acknowledges that the specification is enabling for a synthetic immunogen for inducing specific antibodies against GnRH comprising SEQ ID NOS: 9-20 for the production of high titers of anti-GnRH antibodies. These synthetic immunogens are claimed in new claims 28 and 29.

In the office action, the examiner rejected claims 6, 10, 15 and 17-20 under 35 U.S.C. § 102(b) for alleged lack of novelty over the Ghosh & Jackson (1999) reference of record. Claims 6, 10, 15 and 17-20 have been cancelled. Therefore the rejection of these claims for alleged lack of novelty under 35 U.S.C. § 102(b) is moot and must be withdrawn.

The Ghosh & Jackson reference discloses linear or branched fusion peptides consisting of GnRH amino acid sequences linked either directly or through a lysine residue to any of four T-lymphocyte helper epitopes of tetanus toxin.

Nowhere in the Ghosh & Jackson reference is there any disclosure of a synthetic immunogen comprising amino acids 1-10 or 2-10 of GnRH linked through one of the exemplified spacer peptide sequences (SEQ ID NO: 5, SEQ ID NO: 6 or SEQ ID NO: 7) to a T-lymphocyte helper epitope of measles virus protein F (MVP-F, SEQ ID NO: 8), a T-lymphocyte helper epitope tetanus toxoid (TT, SEQ ID NO: 2 or SEQ ID NO: 4), or a T-lymphocyte helper epitope of malaria circumsporozoite protein (M-CSP, SEQ ID NO: 3). Therefore the rejection under 35 U.S.C. § 102(b) for alleged lack of novelty over Ghosh & Jackson (1999) cannot be applied to new claims 23-36 and must be withdrawn.

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In the office action, the examiner rejected claims 6, 10, 15 and 17-20 under 35 U.S.C. § 102(b) for alleged lack of novelty over the published WO 94/25060 application of Ladd et al. Similarly, nowhere in WO 94/25060 is there any disclosure of the synthetic immunogens of the newly presented claims, 23-36. Therefore the rejection under 35 U.S.C. § 102(b) for alleged lack of novelty over WO 94/25060 cannot be applied to new claims 23-36 and must be withdrawn.

The examiner also rejected claims 6, 10, 15 and 17-20 under 35 U.S.C. § 102(b) for alleged lack of novelty over issued U.S. Patent 5,837,268 to Potter and Manns. U.S. 5,837,268 discloses immunological carrier systems including one or more GnRH multimers or repeating unit of a sequence corresponding to a GnRH epitope fused to a leukotoxin polypeptide. Again, nowhere in U.S. 5,837,268 is there any disclosure of the claims synthetic immunogens of the newly presented claims, 23-36. Therefore the rejection under 35 U.S.C. § 102(b) for alleged lack of novelty over U.S. 5,837,268 cannot be applied to new claims 23-36 and must be withdrawn.

In the office action, the examiner rejected claims 11-12 and 16 and 22 under 35 U.S.C. § 112 second paragraph for alleged lack of antecedent basis. Applicants do not believe that a word-for-word antecedent is required under the Patent Office regulations (MPEP at § 706.03(d)), states that this rejection should only be used in aggravated situations where the lack of antecedent basis makes the claim scope indeterminate. (Emphasis added). However, in the interest of obtaining an early allowance and without conceding to the examiner's argument, applicants have cancelled claims 11-12 and 16 and 22 and presented new claims covering the same subject matter that leave no room for any question of lack of antecedent basis. Claims 11 and 12 drawn to synthetic immunogens for inducing specific antibodies against GnRH have been replaced by new claims 28 and 29 of identical scope. Claim 16, drawn to a pharmaceutical

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composition that includes the combinations of the synthetic immunogens of claim 12 has been replaced by new claim 36 of identical scope.

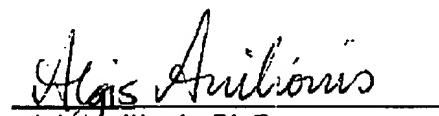
New claims 23-36 are supported throughout the specification, for example at page 5, first three paragraphs, and in the Examples at pages 6-20, including peptides 1-12 of SEQ ID NOS: 9-20 at pages 7-12.

Applicants also enclose a petition for a two month extension of time for response to the final office action of October 6, 2003 and the required fee.

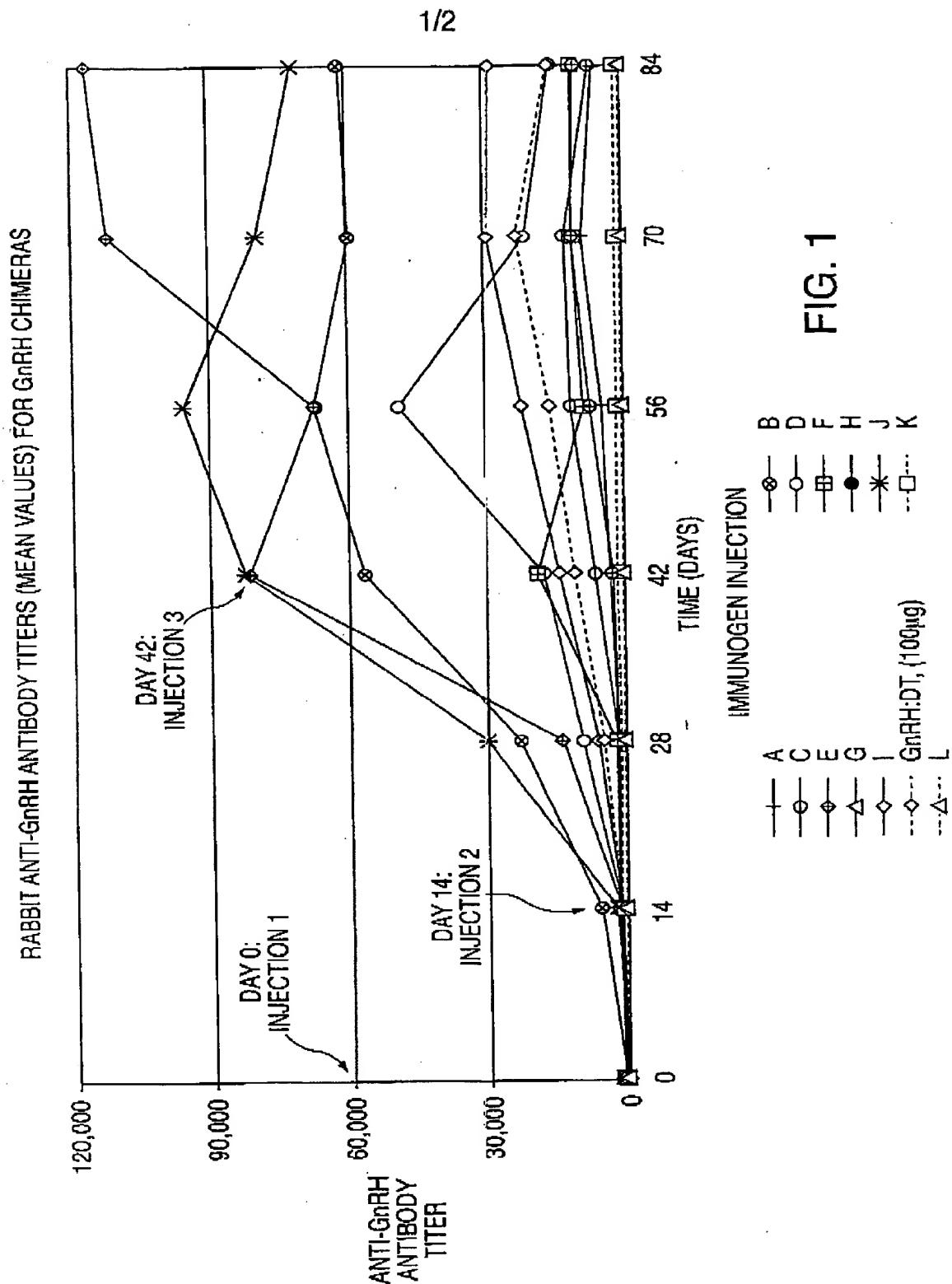
Reconsideration of the final rejection of this application and entry of the amendments made herein is respectfully requested. The Commissioner is authorized to charge any fee which may be due in connection with this response to Deposit Account No. 23-1703.

Dated: March 5, 2004

Respectfully submitted,


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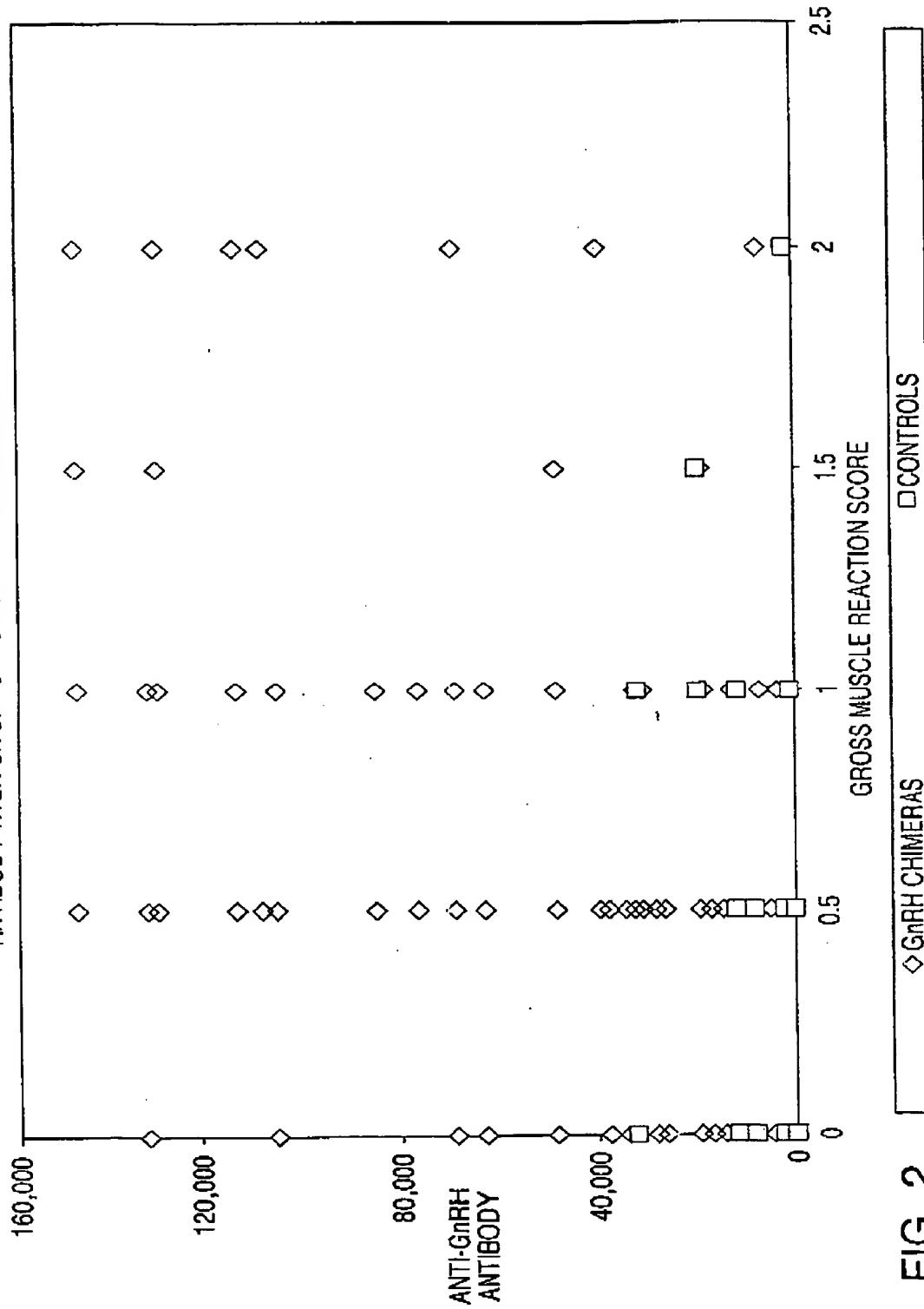
RELATIONSHIP BETWEEN GROSS MUSCLE REACTION SCORE AND MEAN ANTI-GnRH
ANTIBODY TITER ON DAY 84 FOR GnRH CHIMERAS AND CONTROLS

FIG. 2